UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for)
the Use and Benefit of Herself and the Next of)
Kin of Richard Smith, Deceased,)
Plaintiff,) Case No. 3:05-0444
v.) Judge Aleta A. Trauger
PFIZER INC., et al,)
Defendant.)

EXPERT WITNESS STATEMENT OF ROBERT GRANACHER, M.D.

My name is Robert Granacher. I am a psychiatrist from Lexington, Kentucky, and I have been asked to offer opinions on the cause of Mr. Smith's suicide. To briefly summarize my opinions, it is my opinion that Neurontin did not cause Mr. Smith's suicide. Mr. Smith had significant risk factors for suicide that predated his use of Neurontin. These risk factors were not exacerbated in any way by his use of Neurontin. Instead, Mr. Smith's suicide was a result of untreated depression, which was caused in large part by his suffering years of severe chronic pain and enduring multiple major surgeries, including three joint replacements and spinal surgery. He had been treated with 20 different medications for pain-related conditions, none of which provided complete relief. By 2004, Mr. Smith's pain had worsened to the point that he characterized it as "excruciating." A few weeks before his death, Mr. Smith's doctors informed him that he was not a candidate for further surgery. There was no long-term solution for his pain, and he chose to end his life. His suicide was caused by depression, unrelenting pain, and hopelessness, not Neurontin.

Before I explain my opinions in greater detail, I will briefly address my qualifications and experience. I received a Bachelor of Arts degree in Chemistry in 1969 from the University of Louisville, and a Doctor of Medicine Degree from the University of Kentucky in 1972. I then served as resident and chief resident in psychiatric medicine at the University Of Kentucky Following that, I served as a clinical and research fellow in College Of Medicine. psychopharmacology at the Harvard Medical School and Massachusetts General Hospital in Boston. While a fellow at Harvard, I was a senior assistant resident in neurology on the Harvard Neurology Unit at Boston City Hospital for nine months. I am board certified in general psychiatry, geriatric psychiatry, forensic psychiatry, and behavioral neurology and neuropsychiatry. I am also board certified in sleep medicine and clinical psychopharmacology, which is the field of medical science that deals with the diagnosis and treatment of mental disorders with medications.

I practice general, geriatric, and forensic psychiatry, sleep medicine, and neuropsychiatry in Lexington, Kentucky. I am on the staff of the St. Joseph Hospital in Lexington. At St. Joseph's, I am chiefly involved in providing psychiatric consultation to internal medicine doctors and surgeons for patients treated in the intensive care unit, cardiothoracic surgery unit, coronary care unit, and the general medical and surgical floors of the hospital. Thus, my psychiatric consultation is provided primarily to very ill medical and surgical patients and most of the hospital's suicidal patients. In my office practice, I treat 30 to 40 patients each week with various psychiatric and sleep disorder problems. I use many different pharmaceutical agents to treat my patients' problems, including Neurontin. I have prescribed Neurontin since the early 1990s, shortly after it first became available.

As I mentioned, one of my practice areas is geriatric psychiatry. This refers to the psychiatric treatment of older patients. Older patients present several unique considerations in psychiatric practice. They frequently suffer from high burden of disease, including many problems leading to chronic pain. They also exhibit a high incidence of depression associated with their illness. In addition, elderly patients face many losses as they experience the death of family and friends, retirement, social isolation, and loss of physical and mental function. A large percentage of my practice deals with the treatment of elderly patients experiencing chronic pain and depression, similar to that experienced by Mr. Smith.

In addition to treating patients, I teach 4th- and 5th-year psychiatric residents as a clinical professor of psychiatry at the University of Kentucky College of Medicine. I also provide expert consultation services in cases presenting issues related to neurology and psychiatry. I evaluate cases in Canada, the United States, and the Caribbean islands. My current testimony is approximately 52% for the defense and 48% for the plaintiff. One of the services I provide as an expert consultant is the evaluation of workers' compensation cases. I examine three to four workers' compensation cases each week. The majority of those cases involve chronic pain, and more than 50% of these are patients claiming pain related to injuries of the neck or back. I therefore regularly evaluate patients like Mr. Smith, who are afflicted by chronic and debilitating pain.

Throughout my career, I have dealt extensively with the evaluation and treatment of suicidal patients. My current practice as a staff member at St. Joseph Hospital involves the treatment of many seriously ill and suicidal hospitalized patients. For 23 years, I was the psychiatrist on-call to the St. Joseph Hospital emergency department. During that period, I

evaluated all suicidal patients when I was on-call. Finally, I have evaluated and treated varying degrees of suicidality in my private practice patients throughout my career.

I also practice sleep disorder medicine on a daily basis. I developed the St. Joseph Sleep Disorder Center in 1983, and I was the medical director of that center from 1984 to 1996. I currently confine my sleep disorder medicine practice to outpatients only. In addition to serving on the board of directors of St. Joseph Health System, I also serve on the board of governors of the Kentucky Traumatic Brain Injury Trust Fund, the Dean's counsel at the University of Kentucky College of Medicine, and the Interprofessional Education Committee at the University of Kentucky College of Medicine. I also serve on the board of directors of the Kentucky Psychiatric Medical Association, the professional body of psychiatrists in Kentucky. I have been awarded the Distinguished Life Fellow award by the American Psychiatric Association in 2005.

A copy of my professional curriculum vitae, or CV, that lists more details about my education and experience is marked as Ex. 257.

[Demonstrative: Geriatric Suicide Risk Factors]

I will now discuss risk factors for suicide in elderly patients that are important in understanding Mr. Smith's suicide

Studies have demonstrated that the vast majority of suicides are found in patients with diagnosable psychiatric conditions. The classic study by Robins and colleagues demonstrated that 94% of individuals who completed suicide were psychiatrically ill. The majority of those patients had affective disorder or alcoholism. Affective disorders, also called mood disorders, include both depression and bipolar disorder. Other studies have confirmed this strong association between illnesses like depression and completed suicide.

One of the critical factors observed in patients committing suicide, particularly in geriatric patients toward the end of their life, is hopelessness. Hopelessness appears to be strongly associated with suicide in all patients, but particularly in the elderly. There is a synergy between hopelessness and other risk factors, which means that the presence of hopelessness in combination with any other risk factor greatly increases suicide risk.

There also is significant evidence that chronic pain, which is common in depressed older adults, may influence the clinical features of depression and should be assessed as a suicide risk factor. An interesting study in Finnish farmers found an association between back pain and suicidal tendency. The study originally was designed to investigate the relationship between back pain and fatal heart attacks. However, an unexpected outcome of the study was that those subjects who reported back pain during the year before the study initiation had a significantly increased risk of committing suicide during the first ten years of follow-up when compared to patients without back pain symptoms.

A study by Edward and colleagues from John Hopkins University evaluated 1,512 chronic pain patients. Almost one-third of the patients reported some form of recent suicidal ideation. These suicidal thoughts were strongly linked to depression and feelings of catastrophic illness by the patient. In other words, patients who were depressed, and felt that their chronic pain represented a permanent and life altering illness, exhibited a high incidence of suicidal thoughts. These findings were consistent with those of Radcliff and colleagues, who also found that chronic pain conditions were associated with both suicidal thoughts and suicide attempt even in the absence of a recognized mental disorder.

Insomnia appears to heighten the suicide risk created by chronic pain. In one study, chronic pain patients who reported severe and frequent initial insomnia with associated daytime dysfunction and high pain intensity were more likely to report suicidal ideation. This increase in suicidal thoughts was independent for the effect of depression severity.

Chronic pain is also strongly associated with anxiety and depression. World Health Organization data obtained in primary care centers around the world demonstrates that 22% of all primary care patients suffer from persistent debilitating pain and that these patients are four times more likely to have associated anxiety or depression than pain-free primary care patients. Not unexpectedly, the risk of depression is greater when the pain is more diffuse or has a greater effect on the quality of life.

The net effect of these risk factors is that the risk of suicide is greatly increased in elderly patients with severe pain. A large Canadian study found an odds-ratio of suicide in elderly patients with severe pain of 7.52. This means that the presence of severe pain increased the risk of suicide by seven and one-half times compared to similar patients without severe pain. A British review article found eight risk factors associated with increased risk of death and suicidal risk in chronic pain patients. These risk factors for suicidality and chronic pain included: the type, intensity, and duration of pain, sleep onset insomnia co-occurring with pain, helplessness and hopelessness about pain, the desire for escape from pain, pain catastrophizing and avoidance, and problem-solving deficits.

Age also plays a significant role in increasing suicide risk, particularly in patients suffering from chronic pain. The elderly experience significant losses as they pass into advanced age. Loss of function is a particularly important adverse consequence for mental health in elderly patients. Many researchers have documented the complex combination factors at play in issues surrounding loss in the chronically ill population. For example, Dr. Ranjan Roy has published a book describing pain, loss, and suffering in persons with chronic illness.

Geriatric psychiatrists consider it very important to identify depressed individuals early so that reasonable treatment can be accomplished to reduce the risks of suicidality and completed suicide. There is significant experimental evidence indicating that appropriate use of antidepressants in depressed elderly patients has reduced the rate of suicide in the older age group. A very large recent study of U.S. suicide rates by age group from 1970 to 2002 demonstrates a significantly reduced suicide rate in patients over age 65 beginning in 1990. This decrease is associated with an increase in usage of antidepressants in this age group. In fact, between 1990 and 2002, the suicide rate in patients above age 65 dropped from 20.5 to 15.6 per 100,000 patients. This is a decrease of 25%. This is strong evidence of the importance of treating depression in elderly patients by use of antidepressant medications, as well as other methods.

Finally, the availability of lethal means for suicide, such as gun ownership, is an important suicide risk factor. There is a strong positive association between the availability of lethal means and successful completion of suicide. Gun ownership has been positively linked to increased rates of completed suicide and there is a direct relationship between rates of gun ownership and rates of completed suicide.

Turning now to Mr. Smith's specific case, I will tell you the reasons why I do not believe Neurontin caused Mr. Smith's suicide.

As an initial matter, to come to a conclusion that Neurontin caused Richard Smith's suicide, an expert must first conclude that Neurontin is capable of causing suicide. I have read and reviewed the expert reports and testimony of Plaintiffs' and Defendants' experts on that question.

My own opinion is that reliable scientific evidence that Neurontin causes suicide is lacking. I don't believe it does. In my profession, we see a number of patients with chronic pain conditions who develop depression or suicidal thoughts. That was true before Neurontin existed. That can happen regardless of how we treat severe chronic pain, and regardless of any particular type of medication we use. I have never seen anything in my own patients that even hinted that a patient developed depression or suicidal thoughts because of treatment with Neurontin. In my opinion, as a board certified psychiatrist who has prescribed Neurontin for years, the labeling for Neurontin – the package insert that is approved by FDA and issued by the manufacturer – has always had adequate information about the potential risks and benefits of the medication.

But even if I assumed that Neurontin could increase the risk in at least some patients, the facts in this case would still convince me that Neurontin played no role in Mr. Smith's suicide. Let me explain why.

To determine what caused Mr. Smith's suicide, any expert has to consider and rule out alternative explanations for the suicide. The Plaintiffs' expert Dr. Maris acknowledges this principle, but neither he nor Dr. Trimble actually did this analysis.

In my opinion, the rule of parsimony should prevail in this case. The rule of parsimony dictates that the most reasonable and simplest explanation is, within reasonable medical probability, the best explanation. The most reasonable and simplest explanation for Mr. Smith's suicide is a chronic pain syndrome inducing depression.

[Demonstrative: Suicide Note]

It's within the first sentence of Mr. Smith's suicide note: "Pain has taken over my mind and body." Mr. Smith's depression, which, as I will show you shortly, started long before he ever used Neurontin, was inadequately treated or untreated. His depression was not recognized by his family, or to the extent it was recognized, appropriate action was not taken. A few weeks before Mr. Smith's death, his doctors had told him that they had nothing else to offer to treat his chronic pain. Mr. Smith then became hopeless, felt like he had become useless, and that going on was futile. We see those feelings of hopelessness and futility in his suicide note. It is stark and unmistakable: he says "Forgive me, I cannot go on like this!" These feelings of extreme uselessness and futility led him to plan his suicide and to end his life on May 13, 2004.

[Demonstrative: Mr. Smith's Suicide Risk Factors]

I have summarized Mr. Smith's risk factors for suicide in this chart. In terms of well recognized suicide risk factors, the following are present in this case:

- Chronic pain. It is beyond dispute that Richard Smith suffered from severe, chronic pain. During the last year of his life, the pain had significantly interfered with his ability to engage in the activities of daily living. This risk factor predated any use of Neurontin.
- Untreated depression. Mr. Smith's chronic pain led to depression. His depression went untreated. This depression and lack of mental health treatment predated any use of Neurontin.
- Hopelessness. Mr. Smith received some temporary relief from his severe back pain following surgery in April 2003. However, by May 2003 the pain returned, and it continued to be intense and unrelenting right up to his death. He described it as "excruciating." By the end, according to his wife Mrs. Smith, Mr. Smith was very sick and laid up at home with pain. Worst of all, there was no light at the end of the tunnel in this case. In April 2004, a few weeks before he died, Mr. Smith's doctors told him that he was not a candidate for further surgical treatment and that his pain would be managed conservatively. According to Mrs. Smith's testimony, Mr. Smith was told he "would have to learn to manage his pain." This led to extreme feelings of hopelessness for Mr. Smith. These feelings of hopelessness were directly related to his physical condition constant, severe pain, with no promise of relief. His hopelessness had nothing to do with Neurontin.

- **Suicidal ideation.** Mr. Smith had preexisting suicidal thoughts. He expressed suicidal thoughts both before and after he started using Neurontin.
- Age. Mr. Smith was an elderly white male. This group has the highest rate of completed suicide.
- Access to firearms. Mr. Smith had access to guns in his home. This is an important risk factor for suicide.

Let's now look at how each one of these risk factors is borne out by the facts in this case in a little more detail, starting with chronic pain. By "chronic pain," I mean being in pain over a long period of time, months and years.

[Demonstrative: Mr. Smith's Pain Complaints]

On this chart, we see a summary of pain complaints from Mr. Smith's medical records, year by year, doctor by doctor. His records show pain complaints beginning at least as early as the late 1980s. Over the years, his pain persisted and affected more and more areas of his body. His pain and level of debilitation dramatically worsened after a failed back surgery in early 2003 to the point where he was able to do very little in the months before his death.

Mr. Smith's internist, Dr. Cato, treated him from 1989 until Mr. Smith's death in May 2004. Pain issues appear in Dr. Cato's records throughout that 15 year period. These issues began with jaw and pelvic pain in 1989 and 1990. Mr. Smith had pain in his left knee which progressed to the point that it was replaced with a prosthetic knee in November 1993. In October 1995, Mr. Smith complained to Dr. Cato of pain in his chest.

He then developed pain in the right hip. The hip was evaluated in April 1996 and replaced with an artificial hip in May 1996. After his hip replacement, Mr. Smith complained of pain in his arms.

He then developed pain in his right knee which led to right knee replacement in August 1998. In January 1999, Mr. Smith developed left shoulder pain.

In September 2000, he began to complain of left knee pain, a knee that had already been replaced with an artificial knee seven years earlier. During April 2001, Mr. Smith had pain under both of his shoulder blades. In May 2001, Mr. Smith complained to Dr. Cato of neck pain, chest pain, vertigo, and problems sleeping. Dr. Cato prescribed an antidepressant, amitriptyline.

In June 2001, Mr. Smith complained to Dr. Cato of chest muscle soreness and in December 2001 of right shoulder pain. In 2002, Mr. Smith saw a different doctor, Dr. Lawrence, for a torn rotator cuff and ruptured bicep, both very painful, debilitating conditions.

By January 2003, Mr. Smith told Dr. Cato that he was having pain in all of his joints and insomnia. In February 2003, Mr. Smith complained to Dr. Cato of joint and back pain. His back pain led to an attempt to surgically fuse three levels of his spinal column in April 2003. We'll come back to his back surgery and look at that in more detail momentarily.

In January 2004, Mr. Smith complained to Dr. Cato of pain that felt like "pricking" sensations that ran from his back down his legs to his ankles. In February 2004, Mr. Smith had left shoulder pain, complained that it "hurts to move," and suffered from chest tightness, increased blood pressure and physical symptoms that were attributed to his pain. We have just summarized some of the many pain complaints that Mr. Smith voiced to his primary care doctor – just one of many doctors he saw during this time period. Mr. Smith is plainly a man who had many serious pain problems that over a period of years intensified and spread through his body, especially his bones, joints, and muscles. Let's now look closer at his back surgery in 2003 and its aftermath, which I believe is very important to understanding what he went through in his final year.

On February 27, 2003, when he had developed back pain, Mr. Smith consulted with Dr. Hampf, a neurosurgeon. Mr. Smith's chief complaint was severe pain in the hip area, down the

back of the thighs, down the calves, ankles and heels, and occasional pain to the end of his spine. Mr. Smith also reported that he was suffering tingling sensations that made it hard to walk. Mr. Smith told Dr. Hampf that he had injured himself while trying to fix a broken pipe in his bathroom. The pain had begun eight weeks before Dr. Hampf's examination on February 27, 2003. Dr. Hampf diagnosed lumbar stenosis, or narrowing of the canal through which the spinal cord runs, and recommended surgery.

[Demonstrative: Callout of 3/11/03 Note, 000006-52FMB-00052]

Mr. Smith was scheduled for surgery to be performed by Dr. Hampf on April 16, 2003. But as this note shows, Mr. Smith decided to cancel that surgery with Dr. Hampf because he "couldn't wait" for the April 16 appointment because he was "in so much pain."

Mr. Smith was not operated on by Dr. Hampf or his partner, Dr. Berklacich, but instead consulted with Dr. Paul McCombs, who confirmed the diagnosis of spinal canal stenosis. Mr. Smith underwent surgery, a decompressive laminectomy and fusion of three separate levels of his lower spine, on April 3, 2003. This gives us an idea of how badly Mr. Smith was hurting. He was not only willing to try major spine surgery, but found a different doctor who could operate on him two weeks sooner than the doctor who originally recommended the surgery.

[Demonstrative: 5/2/03 Neurosurgical Associates Note, 000006-1PRD-00408]

Mr. Smith's pain initially seemed to improve following surgery. However, that improvement did not last. As documented in this May 2, 2003 record from Dr. McCombs' office, Mr. Smith stated that he "wished he could die because of pain and depression." This is 10 months before Mr. Smith first used Neurontin. The medical records after this point document increasing, debilitating, and demoralizing pain in the year leading up to Mr. Smith's death. Some important examples are as follows:

[Demonstrative: Dr. McCombs Note 5/5/03]

• May 5, 2003. Richard Smith told Dr. McCombs that he is experiencing new symptoms of increased leg pain.

[Demonstrative: Dr. Cato's Notes 5/15/03]

• May 15, 2003. Dr. Cato diagnosed Mr. Smith with anxiety and depression related to his pain. Importantly, this diagnosis of depression occurs <u>before</u> Mr. Smith receives any Neurontin.

[Demonstrative: Dr. Mackey's Notes 2/25/04]

• **February 25, 2004.** Mr. Smith saw Dr. Mackey, an orthopedic specialist, for a second opinion for his severe leg pain. He told Dr. Mackey that his pain was getting worse. Mr. Smith complained of back pain, leg pain, knee pain, and radicular pain, which is pain radiating from the spinal cord and down the leg.

[Demonstrative: Pam Krancer's Notes (Dr. McCombs' Nurse Practitioner)]

• March 2004. Mr. Smith has several visits with Drs. Mackey and McCombs, desperately trying to find some relief for his chronic pain. He is first prescribed Neurontin March 9 at a dose of 600 mg per day, which is a relatively low dose. He complains that neither his epidural steroid injections nor his medications are helping him. On March 24, his Neurontin dose is appropriately increased to 900 mg/day, or one tablet taken three times daily. This is by no means a high dose of Neurontin; the FDA labeling recommends up to twice the dose that Mr. Smith was directed to take at this point. There is discussion of Mr. Smith having more epidural steroid injections, but apparently no records that he actually had and injections from this point forward.

[Demonstrative: Physical Therapy Notes (5/4/04), 000006-35UMC-00076]

• May 4, 2004, about nine days before Mr. Smith took his life, this physical therapy note shows that Mr. Smith at that time described his pain as 7 or 8 out of 10, which is categorized as "excruciating."

[Demonstrative: 5/19/04 Letter by Dr. Woods, 000006-19CLW-00001]

• According to this letter from Mr. Smith's dentist Dr. Woods, written six days after Mr. Smith's suicide at the request of his daughter Cindy, Mr. Smith had seen Dr. Woods on the 10th, about three days before his suicide. According to the letter, Mr. Smith mentioned Neurontin, and said that it made him feel "loopy." We do not know what Mr. Smith meant by that remark. Whatever he meant by it, we cannot tell whether it was Neurontin, one of the other pain medications he was taking at that time, such as the opioid narcotic Lortab, or some other factor that made him feel that way. What is most important to understanding Mr. Smith's suicide is that Mr. Smith told Dr. Woods that an end to pain was hopeless. This is a major, well established risk factor for suicide. Mr. Smith explained that he could not cut grass or work on

cars like he used to. He talked about feeling useless. These remarks are consistent with his wife Ruth Smith's deposition testimony. She explained that in April to May, 2004, Mr. Smith spent most of the day "laying around" because of his severe pain.

To recap the risk factor of chronic pain, the records we have tell a poignant and clear story of Mr. Smith's long battle with painful conditions, which deteriorated steadily during the last year of his life, after his failed spine surgery. These facts help us understand what he meant in his suicide note when he said "Pain has taken over my mind and body."

I will now turn to the second major risk factor, his untreated depression.

[Demonstrative: 2/27/03 Neurological Surgeons New Pt. Questionnaire, 000006-1PRD-00165]

To trace the clinical records showing Mr. Smith's depression, we start in 2003, more than a year before he first used Neurontin, and about 14 months before his suicide. On February 27, 2003, about a month before his spine surgery, Mr. Smith filled out a medical questionnaire for Dr. Hampf, which I've highlighted in this demonstrative. Mr. Smith said that he was "depressed because of pain and lack of sleep." These are Mr. Smith's own words, "depressed because of pain," and again, he described himself that way long before he used Neurontin.

[Demonstrative: 5/2/03 Neurosurgical Associates Note, 000006-1PRD-00408]

On May 2, 2003, the notes from Neurosurgical Associates, Dr. McCombs' office, show that one of Mr. Smith's daughters called to report that her father "wished he could die because of pain and depression." Again, this was long before Mr. Smith used any Neurontin. This is clearly depressed, suicidal thinking related to his pain, the same themes we see in his suicide note 10 months later. On hearing this, Dr. McCombs' office advised Mr. Smith's daughter to take her father to the ER, the emergency room, "for psychiatric evaluation and treatment." This apparently was not done, as there are no records or testimony indicating that he ever was taken to the ER, or for that matter, that he ever got any professional psychiatric help or counseling

whatsoever for his depression and thoughts and statements about wishing for death because of his pain and depression.

[Demonstrative: 5/15/03 Cato Note, 000006-30HMA-00064]

May 15, 2003, two weeks after that call to Dr. McCombs' office by Mr. Smith's daughter about Mr. Smith wishing he could die because of pain and depression, Mr. Smith saw Dr. Cato, who diagnosed Mr. Smith with anxiety and depression. As shown in this demonstrative highlighting the record of the May 15, 2003, visit, Dr. Cato noted that Mr. Smith's pain had not been relieved after a decompressive laminectomy on April 1, 2003. Dr. Cato prescribed two antidepressants, Lexapro and desipramine.

[Demonstrative: 6/27/03 Cato Note, 000006-30HMA-00065]

Dr. Cato saw Mr. Smith about six weeks later, on June 27, 2003, and again noted anxiety and depression. Dr. Cato's note indicates that Mr. Smith had improved overall, but that he had discontinued his Lexapro because he had run out of medication. There is no indication that the antidepressant was continued, and there is no indication that Mr. Smith got any treatment for his depression or anxiety from this point until the end of his life 10 months later.

In my opinion, the Lexapro was discontinued too soon. It takes six weeks for antidepressants to produce permanent improvement in depressive symptoms. The discontinuance of Mr. Smith's Lexapro at six weeks after initiation, even with a positive response, likely led to relapse, as this is the usual effect of stopping antidepressant medication too soon.

Mrs. Smith testified that she did not know that her husband had been given antidepressants by Dr. Cato. From my point of view as a psychiatrist, that is an important fact. This shows Mr. Smith's reluctance to share the details of his depression or use of antidepressants

even with his wife. Mr. Smith was not only a minister, but an elderly minister who came from a different era. Psychiatry and the ministry often did not mix. Mr. Smith was obviously resistant to discussing his psychological distress even with his wife, and resistant to seeking appropriate treatment for that distress. His wife was able only to speculate on his use or lack of use of Neurontin due to his limited communication to her about his treatments. I have treated a number of priests, ministers, and seminary professors over the years, an in my experience, it is difficult for them to admit weakness and difficult for them to admit that God does not answer their prayers asking for relief from depression without medical assistance. In any event, Mr. Smith's depression was left untreated after his six week supply of Lexapro ran out. He never had the psychiatric evaluation that Dr. McCombs appropriately recommended. In geriatric psychiatry, we see this all too often – depression in elderly people is either unrecognized or not adequately treated. That left Mr. Smith exposed to the recurrence of depressive symptoms, and depression is overwhelmingly the leading risk factor for suicide. In Mr. Smith's suicide note we see Mr. Smith's struggle not only with pain, but with the burden of untreated depression that came with it, in his suicide note, where he begins with the frank admission that "Pain has taken over my mind and body."

I will now turn to the evidence for the third major risk factor I mentioned, Mr. Smith's hopelessness.

The content of Mr. Smith's daughter's call to Dr. McCombs on May 2, 2003 is certainly consistent with hopelessness. She told Dr. McCombs' office that her father "wishes he could die because of pain and depression." This is clearly a hopeless statement and the statement was made before the first prescription of Neurontin. Overall, my analysis of the medical records and Mrs. Smith's deposition testimony leads me to the conclusion that Mr. Smith had reluctance, if

not aversion, to seeking any kind of mental health treatment where he would have to share his feelings. There appears to have been reluctance by Mr. Smith to share information about his medical treatment even with Mrs. Smith. Although this couple was married for many years, Mrs. Smith testified that she never knew her husband took Neurontin until after his death. She testified that the only medication she was aware of was his pain medication. She also testified that she did not know that Dr. Cato had prescribed two antidepressants to Mr. Smith.

This information is important because, in my opinion, Mr. Smith was clearly hopeless and depressed. He appears clearly to me to have had a stoic attitude, common to many men from his generation. He never got psychiatric treatment after it was recommended. He did not fully communicate with his wife about his medical problems. Consequently, his family did not have an opportunity to be fully aware of his level of distress – they knew only what he would tell them. A study by Levi and colleagues has shown that individuals with problems sharing feelings with others are at risk for serious suicide attempts. This study was undertaken in survivors of nearly lethal suicide attempts and one can reasonably conclude that persons who complete suicide probably think in a similar fashion.

[Demonstrative: Suicide Note, 000006-23PPR-00003]

In my opinion, Mr. Smith's suicide note clearly demonstrates that he had become hopeless about the prospects for relief of his severe pain. The poignant statement, "Forgive me, I cannot go on like this!" is clearly that of a hopeless man. Again, Mr. Smith's note says at the top of the page, and he double underlined it, that "Pain has taken over my mind and body." These are hopeless statements. He goes on in his suicide note to clarify the basis of his hopelessness. He writes that "I need back surgery, left and right rotator cuffs, right bicep torn, back surgery to

correct pain in legs." But surgery offers no hope at all, because, as he explains, he cannot bear another operation: "I cannot have my body, the temple of the Holy Spirit, cut on anymore."

His pain was severe and unrelenting, and he saw no meaningful options, no source of hope for relief. Mrs. Smith testified that in the last few months of Mr. Smith's life, "for the first time, doctors told him they could do nothing." It is reasonable to conclude that Mr. Smith felt both hopeless and helpless, and in his own words, "useless," as his physicians told him nothing else could be done to structurally correct his pain. He had been treated with Neurontin, opiate pain relievers, other types of pain medications, multiple surgeries, epidural steroid injections, chiropractic adjustments, and physical therapy, with little or no success. After all of it, he was still in excruciating pain, he did not want more surgery, and, in his words, he said "I cannot go on like this." He said so in his suicide note. Recent research has demonstrated that helplessness and hopelessness are significantly associated with suicidal thoughts.

It is my opinion that Mr. Smith's hopelessness was not caused or made worse by Neurontin, but rather, it was brought on by being told by all of his doctors there was nothing they could do to relieve his chronic pain. In fact, from February 2004 to his death in May 2004, it is clear that Mr. Smith and his family were desperately trying to find Mr. Smith some relief from his pain. On March 9, Mrs. Smith, Mr. Smith, Cindy Smith, and one of his sons-in-law all went to see Dr. Mackey to try to address Mr. Smith's pain, mood and functional impairments.

[Demonstrative: 3/31/04 McCombs Note, 00000634NEA-00003]

In March 2004, Dr. Mackey told Mr. Smith that he did not think surgery would help him. On March 31, 2004, Dr. McCombs agreed with Dr. Mackey, telling Mr. Smith that he was not a candidate for any type of surgical intervention and that he would treat him only with conservative therapy.

[Demonstrative: 5/5/04 McCombs Note (with annotations by Mr. Smith)]

Finally, on May 5, just one week before his suicide, Mr. Smith called Dr. McCombs' office once again asking for some relief from his pain. According to Mr. Smith's own handwritten notes on the medical records, which his family obtained from that doctor before Mr. Smith died, and which are called out in this demonstrative, Mr. Smith was told that they had "nothing to offer him" outside of steroidal injections, medication, and physical therapy, none of which were helping his pain.

In my opinion as a psychiatrist, when Mr. Smith learned that his physicians had nothing else to offer him to treat his pain, a sense of hopelessness overtook him and operated synergistically with his untreated depression and chronic pain to cause his suicide. His own statements to family and others indicate that he was contemplating suicide for at least one year, beginning long before he took Neurontin. His suicide note clearly tells us why he took his life. In his own words, pain had "taken over his mind and body." Mr. Smith's note says nothing about Neurontin.

[Demonstrative: Transcript of 911 Call (5/13/04)]

This was also reflected in Ruth Smith's statements to the medical personnel on her 911 call the morning of Mr. Smith's suicide, which is highlighted in this demonstrative. During that call, Mrs. Smith acknowledged that Mr. Smith had been "in so much pain" and been "so sick."

In addition, she told the 911 responder that their youngest daughter had been suffering with cancer and it was just "too much." During the 911 call, Mrs. Smith also acknowledged that Mr. Smith was depressed and had been expressing suicidal thoughts, asking whether God would forgive him if he ended his life.

In sum, there is a clear pattern in which Mr. Smith's pain level continued to increase and the options for treating the pain continued to decrease. That terrible combination – worsening problems, and running out of solutions – resulted in Mr. Smith becoming depressed and hopeless. As he told us in his note, he simply did not feel like he could go on.

Let me now address the evidence I see on the fourth major suicide risk factor that I think explains Mr. Smith's suicide, his suicidal ideation and plans.

[Demonstrative: Neurosurgical Associates Notes – Dr. McCombs (5/2/03)]

As we saw earlier on the subject of depression, on May 2, 2003, Mr. Smith's daughter called Dr. McCombs and said that her father "wishes he could die because of pain and depression." Dr. McCombs' office advised her to take her father to the emergency room for a psychiatric evaluation but there is no evidence that this was done. This is clear evidence of suicidal ideation before Mr. Smith used Neurontin.

[Demonstrative: Police Report (5/13/04)]

According to the police report prepared immediately after Mr. Smith's suicide, which is shown in this demonstrative, one of Mr. Smith's daughters, Cindy Smith, told the investigating officer that Mr. Smith had mentioned to her that he might take his own life on March 1, 2004. There is a similar reference in the medical examiner's report. That statement by Mr. Smith, made two and a half months before his death, also shows clear suicidal ideation that predates Mr. Smith's use of Neurontin. It is important to recall that Mr. Smith did not begin Neurontin until

March 9, 2004. So we have at least two documented instances where Mr. Smith's pain led to suicidal thoughts before he ever ingested any Neurontin.

There is more. Mrs. Smith testified in her deposition that, about three weeks before his death, Mr. Smith asked her "will God forgive me if I just do away with myself?" Like the statements made in May 2003 and March 1, 2004, his question is clearly an expression of suicidal thinking, made weeks before he died.

[Demonstrative: Suicide Note, 000006-23PPR-00003]

Mr. Smith's suicide note is entirely coherent, clear, and telling about his thought process and reasons for deciding to commit suicide. In my more than 30 years of forensic practice, I have reviewed suicide notes too many times to count. Mr. Smith's really stands out to me. His level of clarity and precision in his note is extraordinary when compared to most suicide notes. Mr. Smith's suicide note describes his agony toward the end of his life. He links it directly to his degenerating physical state and, in particular, to pain. As he states at the top of his note, "Pain is taking over my mind and body."

The question before us is what was Mr. Smith's state of mind in the last year of his life? Did he kill himself impulsively or did he progressively become more depressed and plan to take his life? Did Mr. Smith kill himself because one of his several medications put the thoughts in his mind and made him act on those thoughts, or did he come to the conclusion that his doctors could no longer help him to relieve his pain and become hopeless and unwilling to struggle on?

My answer to those questions is that he did not commit suicide because of some impulsive, drug-induced derangement, but because his chronic pain became unbearable, he was out of options to relieve the pain, and, after much thought and struggle, he ultimately acted out of sheer hopelessness – in his words, he felt that he could "not go on like this."

There is nothing impulsive about being in chronic pain for more than two years, being diagnosed with depression in 2003, being treated with two antidepressants but not for a sufficient period of time to be effective, and being told by one's physicians that nothing more can be done to alleviate pain described by Mr. Smith as excruciating. Mr. Smith was clinically depressed. It can be argued by experts what kind of depression this was but without question, whether diagnosed by physicians or recognized by family, he had a mood disorder that occurred before he ever took Neurontin. Mr. Smith's untreated depression and chronic pain led to his suicide. It is well known that elderly patients with depression are the least likely of all patient groups to be diagnosed properly and treated appropriately. Moreover, families have significant difficulty with the burden of dealing with depression in elderly patients and often are not able to recognize it or get appropriate treatment for their loved one. Therefore, whether at the family level or the physician level, depression in an older adult is often unrecognized or improperly treated. This is precisely what happened to Mr. Smith.

The facts of this case suggest to me that Mr. Smith's suicide was in no way the impulsive act of someone under the influence of a drug, but just the opposite, the result of a decision made after long struggle and with a great deal of thought and planning. As we have seen, Mr. Smith, either directly or through a family member, told multiple doctors that he was depressed, long before he ever used Neurontin. He told his wife about thoughts of suicide, wondering if God would forgive him for it. He thought about suicide and expressed his feelings of depression and suicidal thoughts to his daughters at least enough that statements about depression and/or suicide made before he ever used Neurontin appear in the medical records, police report, and medical examiner's report in this case. From these records and the facts documented in them, I can only conclude that Mr. Smith thought about suicide both before and after he used Neurontin, and that

those thoughts came to him many months before his use of Neurontin or his death. I cannot see any basis to conclude that Mr. Smith's suicidality was impulsive or the result of one of his medications.

In addition, Mr. Smith's method of carrying out his suicide also convinces me that his decision to end his life was not an impulsive, out of character act brought on by his medication, but instead, a choice that he made for the reasons he set out in his suicide note. Everything about the way that he chose to end his life was well thought out, organized, and consistent with his character and the things he cared most about in his life, including God and family.

His suicide note itself, for example, is accurate, oriented to actual events in his life, and in the religious and scriptural references, appropriate to his life and ministry. There is not the slightest hint in his note, for example, that he was imagining medical problems that he did not really have, or that he had suddenly abandoned his faith, or that he suddenly began blaming others for the misery that he was in as a result of his pain conditions.

I believe it is clear that Mr. Smith was a family man who loved and cared a great deal about his wife and daughters. Even in the way he decided to end his life, there is evidence of concern for them. That is reflected in his taking the time to leave a note explaining why he had done what he did, explaining that it was because of pain and his own inability to go on, not any slight or shortcoming of theirs, assuring his family that he had prayed and felt assured that, in his words, "God understands," and even going to the effort to put a plastic sheet over the bed. To put it simply, the way Mr. Smith chose to end his life is consistent with considerable reflection, thought, and planning on his part, and inconsistent with the notion that it was an impulsive act brought about by a reaction to one of his medications.

For all those reasons, my opinion, to a reasonable degree of scientific certainty, is that Mr. Smith's suicide was the product of a long battle with chronic pain that left him depressed and hopeless. I do not think Neurontin had any role in causing it.